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APPLICATION NO.	FILING DATE	FIRST-NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,195	09/14/2000	Keith H. Johnson	2000200-0003	2403
7590	01/27/2004			EXAMINER
Eugene Berman, Esq. Silver McGowan & Silver Suite 1204 1612 K Street, NW Washington, DC 20006				GOLLAMUDI, SHARMILA S
			ART UNIT	PAPER NUMBER
			1616	17
			DATE MAILED: 01/27/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Applicant No.</b>	<b>Applicant(s)</b>
	09/662,195	JOHNSON, KEITH H.
	Examiner Sharmila S. Gollamudi	Art Unit 1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 July 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,6-11 and 15-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,6-11 and 15-26 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>14</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

Receipt of Request for Continued Examination and Information Disclosure received on July 16, 2003 is acknowledged. Claims 1-3, 6-11, and 15-26 are pending in this application.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-3, 6-11, and 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Independent claims recite the phrase “pentagonal dodecahedral” wherein at least one dimension is less than 10 nm. This is vague and indefinite; does this phrase pertain to the number of molecules in the cluster or the arrangement of the cluster? Further, the applicant points to Figure 2 in applicant’s specification to exemplify the water nanocluster; however Figure 2 shows a pentagonal decahedral (10 molecules) and not the claimed dodecahedral (12 molecules). The phrase itself is vague; does the cluster have a pentagonal arrangement or a dodecahedral arrangement? The examiner suggests a more descriptive phrase for the arrangement to distinguish it over the art. Further, the examiner points out that the applicant refers to a 20-molecule water cluster; however this is not a limitation in the claims, the claims. Secondly, it is not clear what dimension is being referred to. Is the applicant referring to length and width? Further clarification is requested.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-3, 6-11, and 15-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0916621 by itself or in further view of Lorenzen (5711950).**

EP 0916621 teaches using fine clustered water for compositions such as pharmaceutical and cosmetic and the process of delivering the water formulation. The advantages of using microclustered water are disclosed: the superior ability to disperse oil and fats in order to prepare emulsions. Additionally, the clustered water improves the absorbability of the dissolved substance and is a good drug delivery vehicle. See page 5, lines 5-7. The word cluster means an aggregate of water molecules and a fine cluster means a treatment that reduces the size of the cluster. The water is treated by magnetic fields, electric fields, high frequency waves, etc. See page 3. It is further disclosed that water-soluble surfactants must be added to the water in order to prepare the emulsion (note pg. 2, lines 6-25). The reference teaches water-in-oil emulsions containing microclustered water, surfactants (ethanol, polyoxyethylenecetyl ether, etc.) and cosmetic oils (paraffin or olive). EP 0916621 discloses the compositions in various forms such as creams, gels, and liquids. Further, the reference discloses the use of additives such as fragrances and antioxidants. EP 0916621 discloses the use of borax in one of the compositions for stability of the emulsion. (Note examples 5-10)

The reference does not specify the size of the water clusters.

Lorenzen teaches the process of making microclustered water and using the water for pharmaceuticals and cosmetic/skin products. Lorenzen discloses that under normal conditions, natural clustering of water molecules is short lived and the cluster size is unpredictable. The reference further discloses the microclusters in 3-15 molecule arrangements and discloses that larger clusters lower the biomedical effectiveness. (Note col. 8, lines 30-55). Lorenzen discloses using templates for creating specific molecular arrangements for specific results (col. 1, lines 45-51).

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to manipulate the conditions of EP 0916621's fine water clusters. One would be motivated to do so since the prior art discloses the general conditions of preparing fine water clusters and applying it to cosmetic compositions and it is not inventive to discover the optimum or workable configurations by routine experimentation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of EP and Lorenzen and manipulate the water clusters of EP. One would be motivated to reduce the size of the water clusters since Lorenzen teaches that 3 to 15 molecules are more effective and larger clusters are believed to have lower biomedical effect. Further one would be motivated to look to Lorenzen since Lorenzen teaches that under normal conditions water does cluster.

***Response to Arguments***

Applicant's arguments with respect to Johnson et al have been considered but are moot in view of the new grounds of rejection. However, the merits of EP are discussed below.

Applicant argues that EP does not define fine clusters and this is not a quantifiable number. It is argued that one can assume that the slit size determines the cluster size. Applicant argues that EP is directed towards the use of water clusters to increase dispersion and not directed towards oil-water emulsions. It is argued that the water clusters of the instant inventions are not selected to enhance the dispersibility of the oil but are selected for other unique properties of the water clusters, i.e. antioxidant effect.

First the examiner points out that the claims are directed towards the process of delivering water nanoclusters in an o/w formulation and a o/w emulsion containing the water nanoclusters. Clearly, EP does teach oil-water emulsions and application as set forth in numerous examples. The use of a patent as a reference is not limited to what the patentees describe as their own invention or to the problem they are concerned with. They are part of the literature of the art, relevant for all they contain. See *In re Heck*. Therefore, EP's inventive thrust may be directed to another problem but applicant's problems are clearly addressed in the reference.

The examiner further points out that the function and goal of the oil-water water cluster formulations of the prior art and the instant invention are the same. The prior art utilizes the water clusters to deliver cosmetics to the skin and provides an oil-water composition. Instant invention also claims a process of delivering water clusters to the

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skin and an oil-water composition. Therefore, the prior art and instant invention are geared towards the same goal: The claims are composition claims in regard to structure of the water and the prior art and the instant invention contain essentially the same components and would have the same effect and formation.

Furthermore, the water cluster is produced the same process as that of the instant invention, i.e. via magnetic fields, high frequency waves, etc. Thus, it is implicit that the water clusters will be similar if not the same to the water clusters of the instant invention. The mere change in shape, size, or arrangement of a component or some difference between the properties of structurally similar compounds does not necessarily impart patentability unless unexpected results are submitted showing that the change imparts a unique property. In this instance the similar compound is water.

Applicant argues that there is no motivation to reduce the size of the water cluster in EP. The examiner points out that EP in fact treats pure water to reduce the water clusters and this "fine" cluster provides extra benefits. See page 3. The secondary reference also confirms that the smaller the cluster, the more efficient it is.

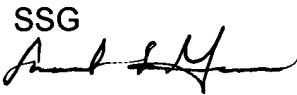
Lastly in regards to the antioxidant benefits, the examiner points out that EP also teaches water clusters and it would also have antioxidant properties of the instant water clusters. Therefore, since both the instant invention and the prior art apply it to the skin, both formulations would have the same effect. Applicant has not shown how the inventive water clusters are different from the water clusters of the prior art.

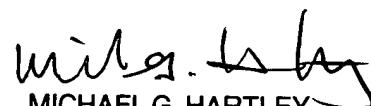
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG  
  
10/8/03

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER